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**BY ECF**

Judge Naomi Reice Buchwald
United States District Court for the
Southern District of New York
500 Pearl Street
New York, New York 10007

**Re: *In re Intercept Pharm., Inc. Sec. Litig.*, No. 14 Civ. 1123**
**(Oral Argument Requested)**

Dear Judge Buchwald,

We are counsel for defendants Intercept Pharmaceuticals, Inc., Mark Pruzanski, and David Shapiro (collectively, "Intercept") in the above-captioned securities fraud action. We write pursuant to Rules 2(E)(1) and 2(F) of the Court's Individual Practices to outline the substantive argument of our motion to dismiss the Consolidated Amended Complaint and to request oral argument on the motion.

The basis for the motion is straightforward: Plaintiffs fail to plead facts supporting a "strong inference"—or indeed any inference—of fraudulent intent. 15 U.S.C. § 78u-4(b)(2)(A); *accord Chill v. Gen. Elec. Co.*, 101 F.3d 263, 267 (2d Cir. 1996). Indeed, the opposite inference—that Intercept acted reasonably and in good faith in waiting until it had actual data about a scientific matter before discussing it—is far more cogent and compelling based on the pleadings and the documents upon which they rely. Because plaintiffs cannot plead scienter, this Court should dismiss the Amended Complaint with prejudice.[1]

Intercept is the developer of a new drug called OCA to treat chronic liver diseases. This action arises out of OCA's success in a government-sponsored trial, the FLINT trial. On January 6, 2014, the trial's sponsor, the National Institute of Diabetes and Digestive and Kidney Diseases ("NIDDK"), informed Intercept that it had decided to stop the treatment phase of the trial, based on a pre-planned interim analysis that showed that OCA's efficacy had crossed a predetermined "early stopping boundary"—*i.e.*, preliminary but strong statistical results showing OCA's efficacy. NIDDK also mentioned that there had been incidences of lipid abnormalities (specifically, higher cholesterol) in the trial patients, and that, based in part on these, NIDDK

[1] Plaintiffs also assert control person liability claims against the individual defendants, which should be dismissed because primary liability cannot be established.

would not continue subjects on OCA after the conclusion of data collection. NIDDK did not provide any details or data about the lipid issues to Intercept, which had no access to data from the interim analysis. On January 9, 2014, Intercept issued a press release—which NIDDK reviewed and approved—describing FLINT's early conclusion. Intercept decided to wait until it had actual data about the lipid issues before discussing them, because it was simply in no position to evaluate these issues or their significance for the prospects of FDA approval, especially in light of similar lipid changes seen in a prior OCA clinical trial that was already public knowledge, and that had formed the basis for selecting OCA for FLINT in the first place. A day later, in response to numerous press requests, NIDDK issued a media statement with further details about the decision. This statement mentioned the lipid issues, but did not include any data or say that lipids had been a reason for stopping the treatment phase of the trial.

The price of Intercept's common stock—which had soared in two days of trading—lost about a fifth of its gains the next day, eventually settling over 300 percent higher than the pre-announcement price. Plaintiffs seek to capitalize on these price fluctuations, and contend that Intercept's decision to wait to disclose the lipid abnormalities amounts to securities fraud.

That contention fails. Plaintiffs allege no possible motive for Intercept to inflate its stock price. And, far from pleading "conscious misbehavior or recklessness," the allegations in the Amended Complaint support the inference that Intercept acted reasonably and in good faith.

Where a securities fraud claim is based on an allegedly material omission, scienter is not established merely by alleging that the defendant knew of the omitted material. *See, e.g.*, *In re Carter-Wallace, Inc., Sec. Litig.*, 220 F.3d 36, 40 (2d Cir. 2000) ("actual awareness" of the omitted information "does not, on its own, constitute 'strong circumstantial evidence of conscious misbehavior or recklessness'"). Rather, a plaintiff must allege that the omission was "at the least, … *highly unreasonable* and … represent[ed] an *extreme departure* from the standards of ordinary care." *Chill*, 101 F.3d at 269. Plaintiffs cannot do so here, because the record is utterly inconsistent with fraudulent intent.

*First*, Intercept shared its draft press release with NIDDK, which reviewed and approved it, telling Intercept it "look[ed] good" and "defer[ring]" to Intercept on whether to discuss lipids.

*Second*, when it issued its press release, Intercept had *no* actual data to indicate that the lipid abnormalities in FLINT had any material scientific significance. Lipid issues are common in patients with liver disease. Intercept had been told that efficacy was the "primar[y]" reason the treatment phase was stopped, and was given no indication at the time that the NIDDK would have otherwise stopped the trial due to safety concerns. Thus, Intercept had no basis to believe that lipid abnormalities would have any impact on OCA's prospects for FDA approval, and decided in good faith not to comment on the lipid issues until it had actual data. *See, e.g.*, *In re Elan Corp. Sec. Litig.*, 543 F. Supp. 2d 187, 217 (S.D.N.Y. 2008) ("Defendants are permitted a

reasonable amount of time to evaluate potentially negative information and to consider appropriate responses").

*Third*, and relatedly, Intercept reasonably believed that OCA's association with lipid abnormalities had long been public knowledge—a belief that Intercept emphasized to NIDDK in contemporaneous emails. Similar lipid changes had appeared in a prior trial of OCA, the results of which were part of Intercept's public SEC filings and had been published recently in a prominent medical journal. *See In re GeoPharma, Inc. Sec. Litig.*, 399 F. Supp. 2d 432, 451-452 (S.D.N.Y. 2005) ("[I]f such alleged misbehavior is incapable of defrauding investors [because it was already public], that, in itself, negates the inference of intent to defraud.").

*Fourth*, Intercept publicly promised in its announcement to release the FLINT results as soon as they were available. And Intercept phrased its statements cautiously, emphasizing that it did not yet have data, and that "[we do] not want to overplay where we are."

Viewed from every angle, the allegations about Intercept's actions are inconsistent with fraudulent intent. The only reasonable inference—and certainly the most compelling one—is that Intercept made a good faith decision with regard to the timing of when to discuss lipids, and had no intent to deceive. Particularly where no possible motive to defraud investors is alleged, the Amended Complaint simply does not support the proposition that Intercept acted in a "highly unreasonable" fashion, or that its actions were an "extreme departure" from ordinary care. As in similar pharmaceuticals cases[2], the Amended Complaint should be dismissed for failure to plead scienter.

Respectfully,

Michael Bongiorno

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[2] *See, e.g.*, *Koncelik v. Savient Pharm., Inc.*, No. 08 Civ. 10262, 2010 WL 3910307, at *7-*8 (S.D.N.Y. Sept. 29, 2010) (allegations that company had recklessly failed to disclose adverse events in drug trial were not as compelling as company's statement that it reasonably believed such events were not significant), *aff'd* 448 F. App'x 154 (2d Cir. 2012) (summary order); *In re AstraZeneca Sec. Litig.*, 559 F. Supp. 2d 453, 470-471 (S.D.N.Y. 2008) (allegations that company failed to disclose negative information about drug's dangers dismissed for failure to plead scienter where there was "nothing whatever to indicate that the statements made did not reflect the honest belief of the authors"), *aff'd sub nom. State Univs. Ret. Sys. v. Astrazeneca PLC*, 334 F. App'x 404 (2d Cir. 2009) (summary order).